



September 30, 2004

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Brush Pkwy.
College Park, MD 20740

OCT 18 2004

Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r) (6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Menopause Support

Studies suggest that soy isoflavones may help relieve hot flashes and night sweats and may help during the transition into menopause. Additionally scientists believe that soy isoflavones are the main contributors to the heart health benefits of soy protein.

on the following product:

YourLife® Soy Isoflavones

Very truly yours,

Leiner Health Products

A handwritten signature in cursive script, reading 'Kristi Ansnes', written over a horizontal line.

Kristi Ansnes
Regulatory Affairs Associate

97S 0162

LET 147417



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(Continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND *Signature™*
Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
BODYCOLOGY™
SAFEWAY SELECT™
Sav•on™
Shaw's
ShopKo®
Spring Valley®
TARGET®
TOP CARE®
TRUNATURE®
Wegmans®